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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,456	03/01/2004	David S. Goldfarb	176/61481 (1-11027-03034)	9599

7590 08/09/2007

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EXAMINER	
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ART UNIT	PAPER NUMBER
1636	

MAIL DATE	DELIVERY MODE
08/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/790,456	GOLDFARB, DAVID S.	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	MAF

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-28 and 59-74* is/are pending in the application.

4a) Of the above claim(s) *13-15,24 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-12, 16-23, 27-28, 59-62 and 64-74* is/are rejected.

7)☒ Claim(s) *26 and 63* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the papers filed 5/18/2007 in which claims 1-2, 5, 7-9, 17, 19-20, 23 and 26 were amended; claims 4 and 29-58 were cancelled; and claims 59-74 were added. Claims 1-3, 5-28 and 59-74 are pending. Claims 13-15 and 24-25 are withdrawn. Claims 1-3, 5-12, 16-23, 26-28 and 59-74 are under examination in the instant Office action.

Any rejection of record not recited herein is hereby WITHDRAWN.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must

be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application Nos. 60/451309, filed 2/28/2003 and 60/466,467, filed 5/6/2003, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, claims 1-3, 5-12, 16-23, 26-28 and 59-73 are not supported by these prior filed documents because neither of the above-recited provisional applications provides support for claim limitations which include (i) test cultures but not control cultures comprising mother yeast cells exposed to any environmental stimulus other than a pro-oxidant or (ii) test cultures but not control cultures which comprise mother yeast cells that possess any genotype modification of either a non-essential gene or an essential gene, in which case the genotype modification is non-lethal, and are exposed to any environmental stimulus other than a pro-oxidant.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. **This rejection is maintained for reasons of record but has been slightly altered and extended to claim 71 in order to accommodate Applicant's amendment.**

Claim 23 recites "…calculating the two-dimensional area or a morphometric property of colonies in each of the images, wherein the two dimensional area or the morphometric property of a colony is proportional to the replicative lifespan of the mother cell" in lines 5-8 (emphasis added). Claim 23 is vague and indefinite in that the metes and bounds of a "morphometric property" are unclear. It is further unclear how such a morphometric property can be "proportional" to the "replicative lifespan" of the mother cell. How can, e.g., an oval-shaped mother yeast cell be "proportional" to the number of times the yeast cell has replicated?

Similarly, claim 71 recites "…calculating the two-dimensional area or a morphometric property of colonies in each of the images, wherein the two dimensional area or the morphometric property of a colony is proportional to the replicative lifespan of the mother cell" in lines 5-7 (emphasis added). Claim 71 is vague and indefinite as explained for claim 23 above.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-12, 16-23, and 26-28 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for identifying an environmental stimulus or a gene that alters the lifespan of yeast, does not reasonably provide enablement for methods of identifying such a stimulus or gene or stimulus/gene combination capable of altering the lifespan of any organism is hereby WITHDRAWN.

Response to Arguments/Declaration under 37 CFR 1.132

Receipt is acknowledged of the Goldfarb Declaration filed under 37 C.F.R. 1.132. Based upon the preponderance of the evidence present before Examiner and in view of the probative nature of the Goldfarb Declaration, the rejection of the claims under 35 U.S.C. 112, 1st paragraph is withdrawn.

Claims 23 and 71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection. This is a new rejection necessitated by Applicant's amendment.**

The specification as originally filed does not provide support for the invention as now claimed: "...calculating the two-dimensional area or a morphometric property of colonies in each of the images, wherein the two dimensional area or the morphometric property of a colony is proportional to the replicative lifespan of the mother cell" (claims 23 and 71). The specification does not provide sufficient blazemarks nor direction for the instant relationship between morphometric

properties and/or two-dimensional areas and replicative lifespan, as currently recited. The instant claims now recite a limitation, which was not clearly disclosed in the specification as filed, and now changes the scope of the instant disclosure as filed. Such a limitation recited in the present claims, which did not appear in the specification as filed, introduces new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 11-12, 19-22 and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by Guarente et al (US Patent 5,847,210).

This is a new rejection necessitated by Applicant's amendment.

Guarente et al teach a method of identifying mutant strains of yeast and compounds that alter the lifespan of (yeast) cells

(see entire document, especially columns 16-18). Guarente et al teach the use of temperature sensitive yeast comprising a mutation in the mdm-2 gene wherein daughter cells bud off from a mother cell and die at the non-permissive temperature (37°C), but grow at the permissive temperature (see column 17, lines 46-67). With regard to claim 74, yeast grown at the non-permissive temperature which formed colonies comprising more than "N" cells, wherein "N" is equal to the number of generations in the life span of the mother cell, would identify the strains comprising a mutant genotype that increases the replicative lifespan of the organism (column 17, lines 54-61). Guarente et al further teach that the use of such temperature-sensitive yeast can be can be employed to identify agents which alter the life span of a yeast strain (see column 18, lines 12-27). As taught by Guarente et al, one of ordinary skill in the art would perform the assay with at least three controls: 1) yeast grown at the permissive temp without the compound; 2) yeast grown at the permissive temp with the compound, and 3) yeast grown the non-permissive temperature without the compound. Yeast grown in the presence of the compound at the non-permissive temperature and which formed colonies comprising more than "N" cells, wherein "N" is equal to the number of generations in the life span of the mother cell in the absence of the compound, would

identify the compound as increasing the lifespan of the organism (column 17, lines 54-61 and column 18, lines 12-27). The cells do not appear to be grown in the presence of galactose. Regarding claims 11-12, the mother cells comprise a mutation in a nucleic acid encoding a mutant protein and the gene is nonessential insofar as the cells with the mutation are still viable. Regarding claim 20, Guarente et al teach such a method wherein the culturing is carried out on a solid growth medium as evidenced by Guarente et al teaching that cells are "plated" at permissive and non-permissive temperatures and insofar as Guarente et al teach the determination of colony size (see paragraph bridging columns 17 and 18). Regarding claims 21-22, Guarente et al teach a method wherein the assessment is done manually by analyzing optical images insofar as the assay is performed by "visualizing growing cells in a microscope and micromanipulating away the daughter cell after each division" and then counting the cells (see column 7, lines 35-47).

Claims 1-3, 5-11, 16, 19-20, 22, 59-62, 64, 67-68, 70 and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by Jarolim et al (1st International Meeting on Yeast Apoptosis, Braga, Portugal, Meeting Abstract, page 1-2, October 4-6, 2002; IDS Ref. #2) as evidenced by Jarolim et al (*FEMS Yeast Research*

5:169-177, 2004). **This is a new rejection not necessitated by Applicant's amendment.**

Jarolim et al teach providing a cell culture comprising yeast K6001 mother cells grown in the presence and absence of galactose, i.e. which are exposed to an environmental stimulus other than a pro-oxidant. The cells are also grown in the presence of galactose. The cells comprise a genotype modification in that the CDC6 gene is deleted and replaced by one copy integrated under the HO promoter and one copy under the GAL1 promoter (see page 1 at "Background" and "Methods"). Jarolim et al also teach such a method wherein the cells further comprise genomic mutations (see "Results and Conclusion"). The cells are then cultured under conditions wherein mother yeast cells can replicate but daughter yeast cells cannot (see page 1 at "Methods"). Jarolim et al teach that optical density determinations reliably correlated with lifespan, (see paragraph bridging pages 1-2). Furthermore, determining whether the mother yeast cells in the test cell culture exhibit a change in replicative lifespan when compared to the mother yeast cells in the control cell culture in the method taught by Jarolim et al would indicate that the genotype modification and/or environmental stimulus increase(s) the replicative lifespan of the organism exposed to the environmental stimulus or possessing

the genotype modification as evidenced by Jarolim et al (*FEMS Yeast Research* 5:169-177, 2004) wherein Jarolim et al teach K6001 yeast with non-lethal genotype modifications shown to have increased replicative lifespans (see entire document, especially page 173, Figure 3). With regard to claims 11 and 62, the mutation is to a non-essential gene insofar as the mutant yeast strains are viable. With regard to claims 16 and 64, growth curve analyses were performed as evidenced by Jarolim et al at Figure 3. With regard to claims 19-20 and 67-68, Jarolim et al teach assessing colony size by determining optical density on microtitre plates. With regard to claims 22 and 70, Jarolim et al (Meeting Abstract) teach "[u]p to now we showed that simple optical density determination on microtiterplates are reliable correlated with lifespan."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-11, 16-20, 22, 59-62, 64-68, 70 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jarolim et al (1st International Meeting on Yeast Apoptosis, Braga, Portugal, Meeting Abstract, page 1-2, October 4-6, 2002; IDS Ref. #2) as evidenced by Jarolim et al (*FEMS Yeast Research* 5:169-177, 2004) in view of Bradley et al (US Patent No. 6,531,289; of record). **This is a new rejection not necessitated by Applicant's amendment.**

Jarolim et al teach a method of identifying an environmental stimulus or a gene that alters the lifespan of an organism consisting essentially of providing a mother yeast cell that is exposed to an environmental stimulus other than a pro-oxidant and/or providing a mother yeast cell that possesses a genotype modification of a non-essential gene or an essential gene, in which case the genotype modification is non-lethal; culturing the cell under conditions whereby mother yeast cells can replicate and daughter yeast cells cannot; and determining with the mother yeast cells exhibit a change in replicative lifespan as explained above. Jarolim et al teach that this determination is made using optical density determinations on microtiter plates and by performing growth curve analyses.

Jarolim et al do not explicitly teach this procedure wherein the yeast are grown in liquid medium, nor wherein the

growth curve analyses are performed by measuring optical density of the liquid growth media.

Bradley et al teach high-throughput screening methods for identifying genes of interest and antifungal agents wherein yeast are grown in liquid media and the growth is measured by following the optical density of the cells in the liquid media (see entire document, especially column 6, lines 40-49). Bradley et al also teach growth of yeast on solid plates for measuring colony formation from single cells (ibid). Thus, as Bradley et al teach, and as would have been known to one of ordinary skill in the art at the time of filing, methods of optical density measurements and growth in liquid or solid media would be obvious design choices.

One would have been motivated to combine the method taught be Jarolim et al for identifying compounds/genes that alter the lifespan of a cell (which requires the exposure of yeast to different agents and monitoring the growth of such yeast both in control cultures and test cultures) with the method taught by Bradley et al for growing yeast in a screening method comprising the use of solid media or liquid media and measuring by optical density to facilitate the quantitative determination of cell growth (growth curves) of multiple cultures/colonies.

Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result when combining the methods of Jarolim et al and those of Bradley et al.

Claims 1-3, 5-11, 16-20, 22, 27-28, 59-62, 64-68, 70 and 72-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jarolim et al (1st International Meeting on Yeast Apoptosis, Braga, Portugal, Meeting Abstract, page 1-2, October 4-6, 2002; IDS Ref. #2) as evidenced by Jarolim et al (*FEMS Yeast Research* 5:169-177, 2004) in view of Bradley et al (US Patent No. 6,531,289; of record) and further in view of Fisher et al (US Patent No 6,200,746). **This is a new rejection not necessitated by amendment.**

Jarolim et al teach a method of identifying an environmental stimulus or a gene that alters the lifespan of an organism consisting essentially of providing a mother yeast cell that is exposed to an environmental stimulus other than a pro-oxidant and/or providing a mother yeast cell that possess a genotype modification of a non-essential gene or an essential gene, in which case the genotype modification is non-lethal; culturing the cell under conditions whereby mother yeast cells

can replicate and daughter yeast cells cannot; and determining with the mother yeast cells exhibit a change in replicative lifespan as explained above. Bradley et al teach high-throughput screening methods for identifying genes of interest and antifungal agents wherein yeast are grown in liquid media and the growth is measured by following the optical density of the cells in the liquid media, as explained above (see entire document, especially column 6, lines 40-49).

Jarolim et al in view of Bradley et al do not teach such methods comprising the use of ten or one-hundred or more test cultures.

Fisher et al teach high-throughput cell-based assays for identification of HPV E7 and CDK2 inhibitors. Fisher et al teach that the assays of their invention are particularly amenable to high throughput screening (HTS) assays wherein tens to thousands or more of compounds can be screened in an efficient manner. Fisher et al further teach that these assays can be yeast-based (see entire document, especially column 6, 1st full paragraph).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Jarolim et al in view of Bradley et al with the teachings of Fisher et al, because both Jarolim

et al in view of Bradley et al and Fisher et al teach high throughput yeast-based assays for screening genes/compounds.

One of ordinary skill in the art would have been motivated to combine the teachings of Jarolim et al in view of Bradley et al with those of Fisher et al because Fisher et al teach that the use of high throughput assays results in efficient screening of "tens to thousands or more" of compounds.

Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result when combining the methods of Jarolim et al in view of Bradley et al with those of Fisher et al.

Claims 1-3, 5-11, 16, 19-22, 59-62, 64, 67-70 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jarolim et al (1st International Meeting on Yeast Apoptosis, Braga, Portugal, Meeting Abstract, page 1-2, October 4-6, 2002; IDS Ref. #2) as evidenced by Jarolim et al (*FEMS Yeast Research* 5:169-177, 2004) in view of Guarente et al. **This is a new rejection not necessitated by Applicant's amendment.**

Jarolim et al teach a method of identifying an environmental stimulus or a gene that alters the lifespan of an organism consisting essentially of providing a mother yeast cell

that is exposed to an environmental stimulus other than a pro-oxidant and/or providing a mother yeast cell that possesses a genotype modification of a non-essential gene or an essential gene, in which case the genotype modification is non-lethal; culturing the cell under conditions whereby mother yeast cells can replicate and daughter yeast cells cannot; and determining with the mother yeast cells exhibit a change in replicative lifespan as explained above. Jarolim et al teach assessing colony size by determining optical density on microtitre plates. Jarolim et al (Meeting Abstract) also teach "[u]p to now we showed that simple optical density determination on microtiterplates are reliable correlated with lifespan."

Jarolim et al do not explicitly teach such a method wherein assessing colony size is performed manually.

Guarente et al also teach a method of identifying mutant strains of yeast and compounds that alter the lifespan of cells wherein yeast cells are cultured under conditions wherein mother yeast cells can grow and daughter yeast cells do not, also as explained above (see entire document, especially columns 16-18). Yeast grown in the presence of the compound at the non-permissive temperature and which formed colonies comprising more than "N" cells, wherein "N" is equal to the number of generations in the life span of the mother cell in the absence

of the compound, would identify the compound as increasing the lifespan of the organism (column 17, lines 54-61 and column 18, lines 12-27). Guarente et al teach such a method wherein the culturing is carried out on a solid growth medium as evidenced by Guarente et al teaching that cells are "plated" at permissive and non-permissive temperatures and insofar as Guarente et al teach the determination of colony size (see paragraph bridging columns 17 and 18). Guarente et al also teach a method wherein the assessment is done manually by analyzing optical images insofar as the assay is performed by "visualizing growing cells in a microscope and micromanipulating away the daughter cell after each division" and then counting the cells (see column 7, lines 35-47). According to Guarente et al this makes it "possible to follow a pedigree from each starting cell" (ibid).

It would have been obvious to one of ordinary skill in the art to combine the methods of Jarolim et al with Guarente et al because both Jarolim et al and Guarente et al teach methods of assessing colony size as an indication of lifespan using assays wherein yeast cells are cultured under conditions such that mother cells can replicate but daughter cells cannot.

One of ordinary skill in the art would have chosen to assess colony-size/lifepan manually as taught be Guarente et al as a means of precisely counting the number of mother cell

replications insofar as Guarente et al teach that the daughter cells are micromanipulated away and that such a method makes "it is possible to follow a pedigree from each starting cell."

Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result when combining the methods of Jarolim et al with those of Guarente et al.

Allowable Subject Matter

Claims 26 and 63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claim is allowed.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy

should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571)

272-4439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Joseph Woitach can be reached at (571) 272-0739.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

August 1, 2007

DAVID GUZO
PRIMARY EXAMINER